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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/403,092 | 10/15/99 | HOFMANN J | 038311/0103 |

HM12/0731

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| EXAMINER | |
|---|---|
| ZEMAN,R | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | 18 |

**DATE MAILED:** 07/31/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/403,092 | Hofmann et al. |
| **Examiner** | **Art Unit** |
| Robert A. Zeman | 1645 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *May 22, 2001*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *17-26 and 29-34* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *17-26 and 29-34* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

## DETAILED ACTION

The amendment filed on 4-30-2001 and the replacement paragraphs filed on 5-22-2001 are acknowledged. Claims 20 and 23-25 have been amended. Claims 27 and 28 have been canceled. Claims 17-26 and 29-34 are pending and currently under examination.

The declaration filed on 4-30-2001 (Paper No. 14) is acknowledged.

### *Objection to Specification*

The objection to the specification for the use of the various trademarks throughout this application is maintained for reasons of record. The amendment to the specification fails to fully address the objection. While said amendment has properly capitalized the trademarks wherever they appear, it fails to provide the requisite corresponding generic terminology.

### *Claim Objections Withdrawn*

The objection to claims 24-25 based on the misspelling of *Dictyocaulus viviparus* is withdrawn in light of the amendment thereto.

### *Claim Objections Maintained and New Objections*

The objection to claim 30 based on the misspelling of *Dictyocaulus viviparus* is maintained. Applicant has failed to address the objection to this claim in his response to the previous Office action.

Claim 24 is objected to for the following minor informalities: said claim has "SEQ I" on one line and "D NO:" on another, with an extraneous "(b)" in between.

### *Claim Rejections Withdrawn*

The rejection of claims 17-26 and 31-34 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Britton et al. (Molecular and Biochemical Parasitology, Vol. 72 No. 1-2, 1995, pages 77-88, IDS-10) is withdrawn. Applicant's arguments and the portion of the Hofmann Declaration directed toward comparison of Britton's Figure 1(a) and Applicant's SEQ ID NO:30 have been fully considered and deemed to be persuasive.

The rejection of claim 20 under 35 U.S.C. 112, first paragraph, based on the specification not reasonably providing enablement for "a part thereof" of the aforementioned isolated protein is withdrawn in light of the amendment thereto. It should be noted that claim, as amended, has been rejected for introducing new matter (see below). If the said claim is further amended to remove said new matter, said claim may again be subject to the original rejection.

### *Claim Rejections Maintained and New Grounds of Rejection*

### *35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to said claim introduces the limitation "immunogenic" part thereof. Said limitation constitutes new matter since no support could be located for this material in the specification as filed, including the portions cited by Applicant which do not disclose an immunogenic part of the protein.

The rejection of claim 23 under 35 U.S.C. 112, first paragraph, based on the specification, while being enabling for an isolated nucleic acid which comprises SEQ ID NO:29, does not reasonably provide enablement for "a part thereof" of the aforementioned isolated nucleic acid is maintained for reasons of record.

Applicant has amended said claim to recite "an isolated nucleic acid comprising SEQ ID NO:29 or a nucleic acid that hybridizes, under stringent conditions, with a nucleotide sequence according to SEQ ID NO:29". Said amendment is insufficient to overcome the rejection. While the amended claim no longer recites "parts of SEQ ID NO:29" the added limitation of "a nucleic acid that hybridizes, under stringent conditions, with a nucleotide sequence according to SEQ ID NO:29" is not enabled by the specification. Said limitation reads on any nucleic acid that hybridizes to a nucleic acid with the sequence of SEQ ID NO:29. The amended claim, therefore, reads on nucleic acids consisting of as few as two nucleotides. Lathe (Journal of Molecular

Biology, 1985, Vol. 183, No. 1, pp. 1-12) teaches a minimum probe lengths of 16-18 nucleotides for mammalian cDNA, and a probe length of 18-20 nucleotides for mammalian genomic DNA. These numbers are based on the estimated numbers of unique sequences in a cDNA library (~107) versus a genomic library (~109). Use of smaller oligonucleotides will result in non-specific hybridization, because the smaller oligonucleotide complementary sequence will no longer be unique. One of skill in the art would not know how to use oligonucleotides of less that 16 or 18 base pairs in length carrying out a hybridization assay. Additionally, said claim would read on all nucleic acids larger is size than a nucleic acid with the sequence of SEQ ID NO:29, that would hybridize to a nucleic acid with a sequence of SEQ ID NO:29, including genomic DNA. Since the specification only describes the use of nucleic acids with the sequence of SEQ ID NO:29 and the specification provides no guidance for making said nucleic acid in accordance with the claimed invention, said specification is only enabling for the nucleic acids with the sequence of SEQ ID NO:29.

The rejection of claims 24-25 under 35 U.S.C. 112, first paragraph, based on the specification, while being enabling for oligonucleotides which comprise SEQ ID NO:8; SEQ ID NO:9; SEQ ID NO:10; SEQ ID NO:11; SEQ ID NO:12; SEQ ID NO:13; or SEQ ID NO:14, does not reasonably provide enablement for "a part thereof" of the aforementioned oligonucleotides is maintained for reasons of record.

Applicant has amended said claims to recite "parts thereof that hybridize with a sequence of the group under stringent conditions". Said amendment is insufficient to overcome the

rejection. While the amended claim no longer reads on "parts of SEQ ID NO: 8-14" (since it now reads on complementary nucleic acids), the added limitation of "parts thereof that hybridize with a sequence of the group under stringent conditions" is not enabled by the specification. Said limitation reads on any nucleic acid that hybridizes to a nucleic acid with the sequence of SEQ ID NO:8-14. The amended claim, therefore, reads on nucleic acids consisting of as few as two nucleotides. Lathe (Journal of Molecular Biology, 1985, Vol. 183, No. 1, pp. 1-12) teaches a minimum probe lengths of 16-18 nucleotides for mammalian cDNA, and a probe length of 18-20 nucleotides for mammalian genomic DNA. These numbers are based on the estimated numbers of unique sequences in a cDNA library (~107) versus a genomic library (~109). Use of smaller oligonucleotides will result in non-specific hybridization, because the smaller oligonucleotide complementary sequence will no longer be unique. One of skill in the art would not know how to use oligonucleotides of less that 16 or 18 base pairs in length carrying out a hybridization assay. Additionally, said claim would read on all nucleic acids larger is size than a nucleic acid with the sequence of SEQ ID NO:8-14, that would hybridize to a nucleic acid with a sequence of SEQ ID NO:8-14, including genomic DNA. Since the specification only describes the use of nucleic acids with the sequence of SEQ ID NO:8-14 and the specification provides no guidance for making said nucleic acid in accordance with the scope of the claimed invention, said specification is only enabling for the nucleic acids with the sequence of SEQ ID NO:8-14.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 20 under 35 U.S.C. 112, second paragraph, as being indefinite by the use of the term"parts thereof" is maintained for reasons of record. Applicant's amendment to said claim is not sufficient to overcome the rejection since said amendment introduces new matter (i.e. immunogenic parts thereof).

The rejection of claims 24-25 under 35 U.S.C. 112, second paragraph, as being indefinite by the use of the term "parts thereof" is maintained for reasons of record.

Applicant arguments have been fully considered and are deemed non-persuasive for the reasons outlined above.

The rejection of claim 26 under 35 U.S.C. 112, second paragraph, as being indefinite by the use of the phrase "expressing the cDNA clone obtained according to claim 24" is maintained for reasons of record.

Applicant argues that the amendment to claim 24 overcomes said objection. Applicant's argument has been fully considered and is deemed non-persuasive. Since it is impossible to know what "clones" would be obtained according to claim 24 (see above), it is impossible to determine the metes and bounds of the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 17-20, 29-31 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over de Leeuw et al. (Veterinary Parisitology Vol. 39 No. 1-2, 1991, pages 137-147, IDS-10) is maintained for reasons of record.

Applicant argues:

The Declaration by Mr. Hofmann (Paper No. 14) demonstrates that the claimed protein is different from that in the cited reference since the protein in the cited reference and a 18kD protein disclosed by Schneider react to the same antibody and the protein disclosed by Schneider has no relation to the protein of the instant invention since the sequences are different.

Applicant's arguments have been fully considered and are deemed to be non-persuasive. The Declaration by Mr. Hofmann (Paper No. 14) has been fully considered but is not found sufficient since it fails to provide for the Examiner's evaluation any factual evidence to support the assertions made in said declaration. The sequence of the Schneider protein, upon which Applicant relies, has not been presented or made of record. Nor have the monoclonal antibody binding results upon which Applicant relies been made of record. Consequently, in the absence of the availability of supporting evidence to the contrary, the rejection over de Leeuw et al. is maintained.

The rejection of claims 17-26 and 29-34 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schnieder (International Journal of Parasitology, Vol. 22 No. 7, 1992, pages 933-938, IDS-10) is maintained for reasons of record.

Applicant argues:

The Declaration by Mr. Hofmann (Paper No. 14) demonstrates that the claimed protein is different from that in the cited reference since the protein in the cited reference and a 18kD protein disclosed by Schneider react to the same antibody and the protein disclosed by Schneider has no relation to the protein of the instant invention.

Applicant's arguments have been fully considered and are deemed to be non-persuasive. The Declaration by Mr. Hofmann (Paper No. 14) has been fully considered and has been found non-persuasive since it fails to provide for the Examiner's evaluation any factual evidence to support the assertions made in said declaration. Consequently, in the absence of **factual evidence** to the contrary, the protein disclosed by Schneider is deemed to be the same as that of the instant invention. The rejection over Schneider is maintained since the sequence data upon which Applicant relies have not been made available for evaluation.

*Conclusion*

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

July 30, 2001